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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,775	02/05/2004	Shuqi Chen	IQA-009.01	7895

25181 7590 01/25/2007
FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
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BOSTON, MA 02110

EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,775	CHEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. In the previous restriction requirement on October 10, 2006, a species election was made with respect to the following species: dilution buffer (drawn to claim 32), suspension buffer (drawn to claim 32), substrate (drawn to claim 32), lysis reagent (drawn to claims 32, 34), neutralization reagent (drawn to claim 32), wash buffer (drawn to claim 32), elution reagent (drawn to claims 32, 33), germination reagent (drawn to claims 32, 35), amplification reagent (drawn to claim 32). After further consideration of the claims, it was noted that this species was incomplete, as it prevented further examination of the claims, particularly with respect to claims 33-35 and 39-43. Therefore, the species election has been withdrawn, a new species election made with respect to the species recited above.

2. This application contains claims directed to the following patentably distinct species: dilution buffer (drawn to claim 32), suspension buffer (drawn to claim 32), substrate (drawn to claim 32), lysis reagent (drawn to claims 32, 34), neutralization reagent (drawn to claim 32), wash buffer (drawn to claim 32), elution reagent (drawn to claims 32, 33), germination reagent (drawn to claims 32, 35), amplification reagent (drawn to claim 32). The species are independent or distinct because they are different types of substances and are used for different purposes and for their different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 generic.

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3. Depending on which of the above species elected, applicant is further asked to select one of the following subspecies: if elution buffer is elected, applicant is required to elect between Tris buffer, water, and buffer suitable for polymerase chain reaction (all drawn to claim 33); if lysis reagent is elected, applicant is required to elect between a guanidinium salt, a chaotropic salt, a red blood cell lysis reagent, a detergent, a chelator, a spore germination reagent, sodium hydroxide, proteinase K, DNase inhibitor, RNase, Rnase inhibitor, anticoagulant, coagulant, protease, germinant solution, and a surfactant (all drawn to claim 34, with germination reagent also drawn to claim 35).

4. Furthermore, applicant is asked to specify which of the segments each reagent would be located. The species are as follows: 1) first segment contains a substrate (drawn to claims 39, 41, 43), first segment contains either a germination reagent (drawn to claim 40), suspension buffer (drawn to claims 40, 41), lysis reagent (drawn to claims 40, 41), neutralization reagent (drawn to claim 40), and dilution buffer (drawn to claims 40, 41, 42); 2) second segment contains a wash buffer (drawn to claims 39, 43), substrate (drawn to claim 40), elution reagent (drawn to claim 41), lysis reagent (drawn to claims 42, 43), dilution buffer (drawn to claim 43), suspension buffer (drawn to claim 43), germination reagent (drawn to claims 42, 43), neutralization reagent (drawn to claim 42); 3) third segment contains an amplification reagent (drawn to claim 39), elution reagent (drawn to claim 39), lysis reagent (drawn to claim 39), wash buffer (drawn to claims 40, 43), amplification reagent (drawn to claim 41), substrate (drawn to claim 42).

It should be noted that if all reagents and the corresponding segments they are located in will determine which of the claims 39-43 are elected and which are withdrawn.

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5. Applicant is advised that a reply to this requirement must include an identification of the species and subspecies that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

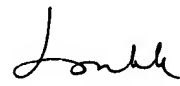
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE 01/22/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600